EFFICACY REVIEW

PRODUCT:

SVP7

REG. NUMBER:

83399-6

DATE:

December 14, 2007

DP BARCODE:

D347318

DECISION NUMBER:

381696

GLP:

N/A

CHEMICAL:

Permethrin (36.08%) Dinotefuran (4.95%)

Pyriproxyfen (0.44%)

CHEMICAL NUMBER:

Permethrin.....109701

Dinotefuran.....044312 Pyriproxyfen....129032

PURPOSE:

Review of label dated December 7, 2007

MRID:

N/A

TEAM REVIEWER:

Rita Kumar

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist

BACKGROUND:

SVP7 is intended for the treatment and prevention of ticks, fleas, and mosquitoes on dogs and puppies over seven weeks of age. The application rate is: 0.06 fl oz for weights 2.5 to 20 lbs., 0.12 fl oz for weights 20 to 55 lbs, 0.16 fl oz for weights 56 to 95 lbs, and 0.3 fl oz for over 95 pounds. The directions for use state that to part the hair between the shoulder blades and to slowly apply the product to the skin until the applicator is completely empty. The number of spots to apply varies upon the weight of the dog. The product should be repeated monthly, and must never be used on other animals, including cats.

RECOMMENDATIONS:

- 1. The following claims are not supported for dogs weighing over 95 pounds and must be either deleted from the label or revised to specify for fleas only.
 - "Quick onset of activity (kill) within 2 hours"
 - "SVP7 contains dinotefuran, a (NEW first 6 months) neonicotinoid insecticide with knockdown in less than 2 hours"

- "Repels and kills up to 100% of mosquitoes for at least one month"
- 2. The following label claims are considered heightened efficacy and must be deleted from the label:
 - "Pyriproxyfen arrests the development of immature flea stages"
 - "Pyriproxyfen metabolically attacks fleas"
- 3. The following claim is not appropriate to be on the label:
 - "Hospital (Clinic) pack (24 and 36 packages only)
- 4. The following label claim contains grammatical/structural errors and must be deleted from the label:
 - "Prevents development of fleas, flea eggs, pupae and larvae for one month or dinotefuran in providing efficacy against fleas, ticks and mosquitoes. Pyriproxyfen is an insect growth regulator which prevents development of all flea stages."

NOTE TO PM....Please note that the DO NOT USE ON CATS statement has been changed from what was previously accepted.